Statement of Chairman Tom Davis
Risk and Responsibility: The Roles of FDA and Pharmaceutical Companies in Ensuring the Safety of Approved Drugs, Like Vioxx
May 5, 2005

Good morning. The Committee is here today to discuss the roles of the Food and Drug Administration (FDA) and pharmaceutical companies in ensuring the safety of approved drugs. More specifically, we will examine the post-approval actions taken by FDA and Merck & Co., Inc. (Merck) related to the arthritis and acute pain medication, Vioxx, and highlight concerns arising from our investigation into the relationship between offices within FDA's Center for Drug Evaluation and Research.

This Committee's investigation began after Merck's September 30, 2004, voluntary world-wide withdrawal of Vioxx. The Vioxx recall came after 5 years on the market, with Merck's annual sales for the drug topping $2.5 billion, and more than 80 million patients having taken the drug. The decision to withdraw Vioxx was made after Merck's own clinical study showed that 3.5% of Vioxx takers suffered a heart attack or stroke, compared with 1.9% of patients taking a placebo. That study followed an earlier study that showed a significant disparity in heart attacks between those patients taking Vioxx and those taking naproxen (commonly sold as Aleve). The earlier study had resulted in the use of new labeling on Vioxx that had been in effect since April 2002.

After the Vioxx study and its ultimate withdrawal, other clinical trials raised serious questions about the cardiovascular risks associated with other COX-2 inhibitors, such as Celebrex and Bextra, and other nonsteroidal anti-inflammatory drugs, such as naproxen. As a result, patients suffering from arthritis or acute

pain were concerned and confused about choosing the proper pain medication. In February 2004, the FDA convened an Advisory Committee meeting to address these concerns.

On April 7, 2005, after reviewing the recommendations of the Advisory Committee, FDA asked Pfizer to remove Bextra from the market and to include a "black box" warning on Celebrex. FDA made no official ruling or recommendation regarding Vioxx since Merck voluntarily removed it from the market.

This brings us to why we are here today. Most average Americans believe that once the FDA approves a drug, that drug carries the Good Housekeeping Seal of Approval. If this were the case, there would be no need for post-marketing surveillance of any drug. Due to the inability of any company to enlist millions of people to participate in pre-approval trials, it is imperative that deliberate post-approval surveillance takes place and that doctors and pharmaceutical companies report to the FDA the adverse reactions of drugs.

As part of its investigation, the Committee requested volumes of documents from and conducted hours of interviews with FDA and Merck regarding post-marketing surveillance. The information obtained has raised questions regarding Merck's knowledge of the cardiovascular risks of Vioxx based on its post-approval research, and how Merck informed the public and physicians of the risk. Merck employed over 3,000 field representatives for the marketing of Vioxx: – did the training materials provided to Merck's sales force adequately cover the cardiovascular risks for Vioxx? Based on those materials, were the representatives presenting a fair and balanced presentation to physicians on the safety of Vioxx? We are pleased to have a Merck representative here today, voluntarily, to answer these questions.

Our investigation also raised questions about the FDA's role in ensuring the safety of drugs after formal approval for sale to the public. Is there a need to strengthen FDA's role in updating safety warnings of previously approved drugs? How do we address these concerns without prematurely depriving millions of people of the benefits that the drug has already demonstrated.

As the Committee conducted its investigation, it became apparent that the relationship between the Office of New Drugs and the Office of Drug Safety has it challenges. It appears that a lack of communication between the offices, as well as communication up the chain of command of these offices has contributed to some discord within CDER (pronounced See-Der). We are pleased to have the Directors of CDER, Office of New Drugs, and Office of Drug Safety here to discuss the steps FDA is taking to address interaction and coordination between the offices, including the creation of the Drug Safety Monitoring Board to monitor post-marketing risks and benefits of drugs.

We aren't here today to point fingers. We are here to explore how drug companies and FDA can work together, and independently, to ensure the best possible post-marketing surveillance of drugs. We are here to ensure that FDA has taken the necessary actions to ensure better communication between the Office of New Drugs and the Office of Drug Safety and that the public is informed regarding the safety of drugs. Finally, we are here to examine Merck's responsibility in informing physicians and the public about the efficacy and safety of Vioxx.